

Appl. No. 10/508,746  
Amdt. dated November 7, 2007  
Reply to Office Action mailed May 7, 2007

### **REMARKS/ARGUMENTS**

Claims 1, 3-7, 9-13 and 15-21 are pending. Claims 2, 8 and 14 have been cancelled without intending to abandon or to dedicate to the public any patentable subject matter. New Claims 15-21 have been added. As set forth more fully below, reconsideration and withdrawal of the Examiner's rejections of the claims are respectfully requested.

#### **Objection to the Specification**

The Examiner has objected to the Abstract, as filed, as composed of two paragraphs. Applicants have amended the Abstract to comply with the guidelines set forth in MPEP 608.01(b).

#### **Rejections Under 35 U.S.C. § 112, Second Paragraph**

The Examiner has rejected Claims 1-14 under 35 U.S.C. § 112, second paragraph, as being generally narrative and indefinite. Claims 2, 8 and 14 have been cancelled. Claims 1, 3-7 and 9-13 have been amended to correct the grammatical errors present in those claims. Applicants therefore submit that the pending claims are sufficiently definite to meet the requirements of 35 U.S.C. § 112, second paragraph.

#### **Claim Rejections Under 35 U.S.C. § 102**

The Examiner has rejected Claims 1-14 under 35 U.S.C. § 102(b) as being anticipated by Ortiz (WO 02/03892). The Examiner submits that Ortiz discloses (at Figures 39A-39D) an annuloplasty device having band or ring type inner and outer portions that act as stabilizers. The Examiner also notes that the device of Ortiz is described as containing fabric or shape-memory alloy materials.

The device of Ortiz is directed to the treatment of different vascular pathologies than the currently claimed device of the present invention. Specifically, the Ortiz device is particularly suited to the stabilization of the atrioventricular valve, whereas the currently claimed device is directed to stabilizing vascular valves by stabilizing both the diameter of the aortic annulus and the diameter of the sinotubular junction.

The heart contains two valve types: atrioventricular valves (i.e. mitral valve and tricuspid valve) and vascular valves (i.e. aortic valve and pulmonary valve). Atrioventricular valves have valve substructures, such as chorda and papillary muscles, but vascular valves have sinuses of valsalva, without any valve substructure. Additionally, the atrioventricular valve is opened and closed by a pressure difference, whereas a vascular valve is opened and closed by twisting of the blood vessels. Thus, the atrioventricular valve, which the Ortiz device is designed to stabilize and the vascular valves, which the currently claimed device is designed to stabilize have completely different structures and gating mechanisms. Therefore, methods and devices used to repair atrioventricular valves are not generally useful for repairing vascular valves. This is why methods and devices of repairing atrioventricular valves, such as the mitral valve and tricuspid valve, are widely used, whereas methods and devices for repairing vascular valves, such as the aortic valve and pulmonary valve, are rarely used. The pending claims have been amended to recite the structural differences that separate the Ortiz and the currently claimed devices and the methods of using these devices, as follows:

**1. Claim 1 recites a combination of two kinds of repair apparatuses**

The currently pending claims are directed to a vascular repair apparatus that contains at least two kinds of repair apparatuses, that is, 1) an aortic annulus repairing apparatus that stabilizes the diameter of the aortic annulus and, 2) a sinotubular junction repairing apparatus and stabilizes the diameter of the sinotubular junction. Because this device consists of both the aortic annulus repairing apparatus and the sinotubular junction preparing apparatus, it can simultaneously stabilize both the diameter of the aortic annulus and the diameter of the sinotubular junction.

In a normally functioning heart, a ratio of the diameter of the sinotubular junction to the aortic annulus is in the range of about 1:11 to about 1:12 when the aortic valve is closed. Using the device of the present invention, the aortic annulus repairing apparatus stabilizes the diameter of the aortic annulus while, at the same time, the sinotubular junction repairing apparatus stabilizes the diameter of the sinotubular junction, such that the ratio of the diameter of the sinotubular junction to the aortic annulus falls within the “normal” range noted above.

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In contrast, the device disclosed by Ortiz is composed of a single comprehensive kind of repair apparatus. That is, the device of Ortiz is a singular repairing apparatus that stabilizes only the diameter of the atrioventricular annulus and therefore cannot stabilize two or more annuli, particularly, the sinotubular junction, and therefore cannot maintain the diameter of the sinotubular junction to the aortic annulus within the "normal" range noted above.

**2. Claim 13 requires stabilization of both the inside and outside of the blood vessel**

The currently pending method of treatment (claim 13) recites a method of treating a vascular valve, wherein the inside and the outside of the blood vessel are stabilized by implanting an aortic annulus inner stabilizer of the band type on the inside of the aortic lumen and placing an outer felt stabilizer on the outside of the aortic lumen. This is in direct contrast to the device and treatment methods of Ortiz, in which the Ortiz apparatus is applied to the upper part and the lower part of the atrioventricular valve within the blood vessel. Thus, the methods of applying and using the apparatus of the present invention and the apparatus of Ortiz are quite distinct.

In light of these differences, recited in the presently pending claims, Applicants submit that Ortiz does not anticipate the pending claims, as amended, and request that the Examiner's rejection under 35 U.S.C. § 102(b) be withdrawn.

Based at least upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,  
SHERIDAN ROSS P.C.

By: /Robert D. Traver/  
Robert D. Traver  
Registration No. 47,999  
1560 Broadway, Suite 1200  
Denver, Colorado 80202-5141  
(303) 863-9700

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